

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

51-2-0085

FORM APPROVED
OMB NO. 0579-0036

DEC 21 2009

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA include Zip Code)

AFG Biosolutions, Inc.
9119 Gaither Road,
Gaithersburg, MD 20878

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

NONE

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in those animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13 Other Animals					
MICE			60	240	300

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF CEO OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

(b)(6), (b)(7)c

12/15/09

Attachment to the APHIS Form 7023

An explanation of the procedures producing pain or distress in those animals and the reasons for anesthetic, analgesic, or tranquilizing drugs were not used (section E)

Our laboratory has established a lethal model of anthrax infection in DBA2 mice using *B. anthracis* (Sterne). Experiments in mice on protection against anthrax are commonly considered the first step in the evaluation of potential therapies, and interpretation of these experiments can be adversely affected by the use of anesthetic, analgesic, or tranquilizing drugs. We used approximately $10 \times LD_{50}$ of anthrax spores intraperitoneally, which corresponds to 1×10^7 spores/mouse (8-9 weeks old). In these conditions approximately 80% animals die within 4-5 days, and the results of different treatment regimens on survival can be monitored reliably and with high sensitivity. For example, ciprofloxacin administration at 50 mg/kg, i.p., for 10 days starting day 1 post infection provides 50% protection after day 14.

The experiments included groups of mice challenged with the pathogen and followed by the treatment with either ciprofloxacin alone (50 mg/kg, i.p., for 10 days starting day 1 post infection) or the combination of the antibiotic and the antibodies. During the experiment, the mice were monitored and checked twice daily, including weekends. Moribund mice with symptoms including lethargy, severely arched back and temperature drop of more than 5°C were sacrificed to relieve pain and suffering. Mice were sacrificed by asphyxiation with CO₂ in accordance with the AFG Biosolutions' IACUC and the 2000 AVMA Panel on Euthanasia. Pressurized CO₂ was used and delivered at 10lbs/inch². All necessary efforts were made to minimize discomfort, distress, pain, or injury to study animals.

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